U.S. Department of Veteran Affairs Office of Research and Development Meeting of the National Research Advisory Council (NRAC) March 3, 2021

Minutes

Committee Members

Dr. Geoffrey Ling, Chairman

Dr. Sanjay Doddamani

Dr. Steven Dubinett

Dr. Carrie M. Farmer

Matthew Kuntz, JD

Dr. Jerry S.H. Lee

Dr. James W. Lillard

Dr. Maria F. Lima

Dr. Ross McKinney

Dr. Ronald Poropatich

Dr. Paula Schnurr

Catherine A. Wicklund, MS

Speakers

Dr. Rachel Ramoni

Dr. Christopher Bever

Dr. Mark Roltsch

Dr. Cendrine Robinson

Ricardo Gonzalez

Dr. Molly Klote

Dr. Sumitra Muralidhar

Kimberly Collins

Attendees

Marisue Cody, DFO

Rashelle Robinson, Alternate DFO

The virtual meeting of the VA's National Research Advisory Council (NRAC) took place on March 3rd, 2021. Designated Federal Officer Marisue Cody opened up the meeting with a couple of announcements about the presentation materials and details on the public comment period. She then invited Dr. Geoffrey Ling, Chairman, to make opening comments.

Chairman Ling, called the meeting to order. He then introduced Dr. Rachel Ramoni for opening remarks.

Dr. Ramoni started by noting this meeting is occurring almost exactly one year from the first time NRAC spoke about COVID and developed the COVID-19 response team which has been meeting regularly ever since. She spoke about some of the accomplishments of the group, including its involvement in several VA and non-VA sponsored clinical trials. She also spoke about the development of SHIELD, a biorepository for COVID.

Dr. Ramoni also spoke about the future for COVID lessons learned and for the NRAC goals including the VA Innovation and Research Review System (VAIRRS) which provides clear visibility on VA and Non-VA funded research. She took a moment to thank the NRAC board for its ongoing feedback in how the VA can continue to grow and improve and credit them with many of the steps that they are taking towards transitioning into a true enterprise.

Dr. Bever presented next on the five-year plan to eliminate or reduce the use of sensitive animal species in VA research and establish a sensitive species subcommittee for NRAC. He spoke about some background on the issue and history of sensitive animal usage, and some solutions to replacing these animals in the studies they are currently being used in. He mentioned for instance, the program at the National Center for Advancing Translational Science's large collaboration with DARPA and the FDA to develop microphysiologic systems to replace animals.

Dr. Bever next explained the specific plans of the VA, which started with establishing an education and mentoring program for VA investigators to inform them of the program's goals and objectives and support them in reducing the use of sensitive animal species in their research. They will also enhance the review process to investigate more closely the evidence on why no other species could be used, as well as analyzing the animal harms versus human benefits. And finally, they will look into ways to reduce or eliminate the use of sensitive animal species through various mechanisms and partnerships that could fill this role.

The last item he mentioned was the development of an ORD Sensitive Species Executive Committee under the NRAC which will include at least one NRAC member, the Chief Research and Development Officer, the Directors or BLRD and RR&D, and VA Chief Veterinary Medical Officer, and at least two senior VA investigators from the field. The Committee's role would be to receive reports from the working group on the VA's progress and report back to NRAC who would then report back to the Secretary of the VA.

Following his presentation there was substantial conversation on the topic, starting with Chairman Ling asking about the transition to companion animals, rather than purpose bred. Dr. Bever explained the goal would be to find animals already suffering from the diseases rather than producing disease in otherwise healthy animals. There followed some discussion about switching from sensitive animal models to other animal models as a solution. They also discussed the importance of pushing for these animal models when it's really important work. The discussion ended with the plan to find an NRAC volunteer moving forward to work on the subcommittee.

Dr. Romani then introduced Mark Roltsch and Cendrine Robinson to speak on the work they are doing with the Diversity, Equity, and Inclusion Working Group. Dr. Roltsch spoke first about the steps they have taken since the last meeting, including finalizing the speakers for their VA early career investigators proposal workshop, and launching their research supplements. Dr. Robinson then spoke about the development of the stakeholder engagement group which will ensure all initiatives are appropriate for the targeted populations. Dr. Robinson and Mr. Gonzalez spoke about the Working Groups ongoing efforts to utilize contracts to help the VA with its diversity initiative and is currently focused on a VA-wide National Diversity Internship Program to help bring diversity in from the very beginning.

Dr. Robinson also spoke about an article called "Fund Black Scientists" and reflected on how the conclusions from that article are further spurring them to push on this diversity initiative to address this lack of funding for black scientists and other minority groups. There was some discussion following with members saying they are happy the peer review process is getting analyzed in a diversity manner to see how and where the VA can improve, but also recognize the challenges that come along with pushing people towards administrative work who would rather be focused on their own science. The discussion ended with the consensus of putting together a list of recommendations for improving diversity and having NRAC approve them and send them up to the Secretary of the VA.

Dr. Molly Klote spoke next on the NRAC's subcommittee focused on diversity and inclusion as it relates externally to research participants. She explained the subcommittee has been focused on notifying minority groups across the VHA of research studies that are occurring in hopes of gaining more diverse participants. They have found that some groups are reluctant to take part due to a history of being forced into dehumanizing studies. The subcommittee is hoping that community outreach and education and a commitment to transparency will encourage new generations to take part again and help develop treatments for, and understandings of different communities.

One of the first projects this subcommittee hopes to tackle is increasing the number of women veterans enrolled in the Million Veteran Program. And in general the approach will be to find studies that exist and find demographics that are lacking and develop an appropriate plan to promote the study to the appropriate communities. Dr. Klote however, explained that as a subcommittee of the NRAC, all recommendations would have to be run up to the NRAC before they made any formal decisions regarding any particular outreach.

Having finished the run through of the various aspects of the Diversity, Equity, and Inclusion Working Group, the NRAC discussed a list of recommendations set forth on progressing on these plans and goals, with Chairman Ling giving everyone a week to issue concerns regarding the recommendations, and hearing none ensuring the understanding that the list would then be forwarded up to the Secretary of the VA.

After break, Dr. Muralidhar spoke on ORD's activities in response to the Commander John Scott Hannon Veterans Mental Health Care Improvement Act. Section 305 of the act requires the VA to establish a precision medicine initiative to identify and validate brain and mental health biomarkers. The Act caused the VA to launch the mental health precision medicine initiative under the umbrella of the Million Veteran Program titled Measures Investigating Neuropsychiatric Disorders (MVP-MIND). The new program will specifically focus on participants with depression, anxiety, PTSD, schizophrenia, bipolar disorder, and substance abuse disorders, as well as those with traumatic brain injury, both mild and moderate forms.

Dr. Muralidhar then added some details on how veterans will be admitted to the MIND program upon their entry into the MVP program, which involves additional surveys, blood specimen collection, and an in depth medical history. The hope is that the infrastructures in place for MVP will help speed up and streamline the process of finding MIND participants. Finally, Dr. Muralidhar explained the various biospecimens and phenotype data that they are collecting and the current repositories they will utilize for collection and storage, as well as an additional emphasis on FMRI and EEG data.

To finish, Dr. Muralidhar explained they were also working with University of Chicago to create a VA data commons that would make the MVP-MIND data available not just to VA researchers but non-VA researchers as well, and then briefly touched on the timeline for the project. Some discussion followed as NRAC members had some clarifying questions on the timeline, the data commons, possible NRAC involvement, and IT limitations.

Dr. Kim Collins spoke last on the extramural funding NRAC subcommittee. The two main recommendations for the subcommittee were to strengthen partnerships and guide decision-making abilities with non-profit and academic affiliates. In order to accomplish these goals, the subcommittee was asked to first develop a white paper that delves into best practices gleaned from years of academic affiliate relationships, and the to develop a toolkit that would allow these partnerships to be formed.

She then briefly touched on the subcommittee makeup and explained it includes both VA individuals, as well as people from a non-federal realm. She explained the process they are following to develop the white paper, which started with creating eight sections of stakeholders and then sent out a focus group letter to those in each stakeholder section. They are now working through hosting focus groups with these various stakeholders in order to learn from their experiences and gathering examples of approaches that worked and ones that didn't. These focus group results will then inform the white paper draft and the toolkit development.

Some discussion about funds brought into the VA through non-profit partnerships followed, and a few NRAC members inquired into some examples of best practices and Dr. Collins explained that they are working on putting those together and will bring them to the NRAC committee soon.

Chairman Ling and Dr. Cody opened the floor to public comments, but there were none.

The meeting adjourned at 1:43 p.m.

Submitted.

Geoffrey Ling, M.D., Ph.D., Colonel, US Army (retired)

Chair, National Research Advisory Council